MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED PROGRAM ANNUAL ACTIVITY REPORT

October 2001 Through September 2002 (FY2002)

Michigan Department of Community Health



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EXECUTIVE SUMMARY

One of the Michigan Department of Community Health's (the "Department" or "MDCH") responsibilities under the Certificate of Need (CON) law is to publish an annual activity report. This is the Department's fourteenth report, and it covers the period beginning October 1, 2001 through September 30, 2002 (FY2002). Data contained in this report may differ from prior reports due to updates subsequent to each report's publishing date.

Historical Overview

In 1974, Congress passed the National Health Planning and Resources Development Act (PL 93-641) that encouraged states to establish a CON program as a vehicle for health services planning. The law was repealed in 1986. Michigan's law was not repealed, and during the 1980s, it became evident that the expectations and decisions of Michigan's CON program were unclear and unpredictable to many applicants. As a result, the CON Reform Act of 1988 was passed that created a systematic standards development system and reduced the number of services requiring a CON. Subsequent to these reforms, the number of CON applications has declined, fewer denials are appealed, fewer unnecessary or clearly inadequate applications are filed, and not a single decision has been overturned in court. The rest of this report describes recent trends and current activities of Michigan's CON program.

Administration

The MDCH's Certificate of Need Section (the "Section") of the Research and Legal Affairs Division, Policy and Legal Affairs Administration, Department of Community Health, provides support for the CON Commission (the "Commission") and its ad hoc advisory committees. The Commission is responsible for setting review standards and designating the list of covered services. The ad hoc committees provide the Commission with expert advice pertaining to the standards.

The MDCH CON Section also manages all incoming applications and letters of intent, determining if CON is necessary and providing the necessary application materials.

Finally, the Special Audits, Review and Compliance Section of the Office of Audit reviews the financial components of CON applications.

CON Application Process

To apply for a CON, the following steps must be completed:

- ' Completion of a Letter of Intent
- ' Filing of application
- ' Review by the CON Section
- ' Issuance of proposed decision on the application that will become binding unless appealed or overturned by the MDCH director in the final decision.
- Issuance of the final approval or denial by the MDCH Director. If a proposed denial is appealed within 15 days of receipt of the proposed decision, the MDCH director will not issue a final decision.

Types of Reviews

There are three types of CON review: nonsubstantive (involving replacement of equipment or change in ownership not requiring a full review), substantive individual, and comparative (involving competitive applications for limited resources by two or more applicants). The administrative rules for the CON program establish time lines by which the Department must issue a proposed decision on each CON application. The proposed decision for a nonsubstantive review must be issued within 45 days of the date the review cycle begins, 120 days for substantive individual, and 150 days for comparative reviews.

In FY2002, there were 82 applications for nonsubstantive review, 145 substantive individual, and 3 comparative, for a total of 230 CON review applications.

Proposed Decisions

In FY2002, 203 applications for CON review were approved, 8 approved with conditions, and 48 disapproved. Of the 48 applications disapproved, 5 were approved upon appeal and final decision or reconsideration, 2 were confirmed as disapprovals, 9 were withdrawn, and 32 applications are still in process.

<u>Report</u>

The following report presents detailed information about the nature of these CON applications and decisions. Note that the data presented in this report represents pass through--some applications were carried over from last fiscal year and others have been carried over into next fiscal year.

HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM

In 1974, Congress passed the National Health Planning and Resources Development Act (PL 93-641) including funding incentives that encouraged states to establish a CON program. The purpose of the act was to facilitate recommendations for a national health planning policy. It encouraged state planning for health services, manpower, and facilities. And, it authorized financial assistance for the development of resources to implement that policy. Congress repealed PL 93-641 and certificate of need in 1986. At that time, federal funding of the program ceased and states became totally responsible for the cost of maintaining CON.

Michigan has had a state CON program since the early 1970s. Over the years, the law has been amended several times. The goal of the program is to balance cost, quality, and access issues and ensure that only needed services are developed in Michigan. However, the program's ability to meet these goals was significantly diluted by the fact that most application denials were overturned in the courts. In order to address this, Michigan's CON Reform Act of 1988 was passed to develop a clear, systematic standards development system and reduce the number of services requiring a CON.

Prior to the 1988 CON Reform Act, the Department found that the program was not serving the needs of the state optimally. It became clear that many found the process for developing planning policies to be excessively unclear and unpredictable. To strengthen CON, the 1988 amendments established a specific process for developing and approving standards used in making CON decisions. The CON review standards establish how the need for a project must be demonstrated. Applicants know before filing an application what specific requirements must be met.

The CON Reform Act created the CON Commission. The CON Commission, whose membership is appointed by the Governor, is responsible for approving CON review standards. The Commission also has the authority to revise the list of covered clinical services subject to CON review. The day-to-day operations of the program, including making decisions on CON applications consistent with the review standards, are carried out by the CON Section of the MDCH. In 1993, additional amendments required ad hoc committees to be appointed by the Commission to provide expert assistance in the formation of the review standards.

The CON program is now more predictable so that applicants reasonably can assess, before filing an application, whether a project will be approved. There are far fewer appeals of Department decisions, and to date, not a single decision under the reformed CON law has been overturned in court. Moreover, the 1988 amendments appear to have reduced the number of unnecessary applications, i.e., those involving projects for which a need cannot be demonstrated.

This development process now provides a public forum for consideration of cost, quality, and access and involves organizations representing purchasers, payers, providers, consumers, and experts in the subject matter. The revised standards development process has resulted in CON review standards that are legally enforceable while assuring that standards can be revised promptly in response to the changing health-care environment. The 1988 amendments also significantly reduced the types of projects subject to CON review.

Trends in CON activity in recent years are characterized in the balance of this report.

Administration of the Certificate of Need Program

Certificate of Need Section, Research and Legal Affairs Division

Certificate of Need Commission Responsibilities

The CON Section provides professional and support staff assistance to the CON Commission and the ad hoc advisory committees in the development of new and revised standards. Staff support includes researching issues related to specific standards, preparing draft standards, and performing functions related to both Commission and committee meetings.

The CON Commission is a five-member body, appointed by the Governor and confirmed by the Senate, responsible for approving CON review standards used by the Department to make decisions on individual CON applications. The Commission also has the authority to revise the list of covered clinical services subject to CON review. <u>Appendix I</u> is a list of the CON commissioners.

Pursuant to the 1993 amendments to the CON law, ad hoc advisory committees are appointed by and report to the CON Commission. The ad hoc advisory committees advise the Commission regarding creation of, or revisions to, the standards. The committees are composed of a majority of experts in the subject matter and include representatives of organizations of health-care providers, professionals, purchasers, consumers, and payers.

Certificate of Need Application Responsibilities

The CON Section has operational responsibility for the CON program. Staff members provide assistance to individual applicants prior to and throughout the CON process.

CON staff is responsible for reviewing all letters of intent (LOI) and CON applications as prescribed by the administrative rules. Based on the LOI, staff determines if a proposed project requires a CON. If a CON is required, staff sends the appropriate application forms to the applicant for completion and submission to the Department. The application review process includes the assessment of each application for compliance with all applicable statutory requirements and CON review standards and preparation of a report documenting the analysis and findings.

In addition to the application reviews, the Section also reviews requests for amendments to approved CON applications as allowed by rules. Amendment requests involve a variety of circumstances including changes in the scope of an approved project, changes in how an approved project is financed, and authorization for cost overruns. The rules allow actual project costs to exceed approved costs by a specified amount due to the difficulty in estimating construction and other capital costs at the time an application is filed. Currently, no fee is charged for processing amendments.

The Section provides the Michigan State Hospital Finance Authority (MSHFA) with information when hospitals request financing through MSHFA-bond issues and Hospital Equipment Loan Program (HELP) loans. This involves advising MSHFA on whether a CON is required for the activities that will be financed through MSHFA or if a required CON has been obtained.

Special Audits, Review and Compliance Section, Office of Audit

In addition to the review conducted by the CON Section, the Special Audits, Review and Compliance Section, Office of Audit, reviews the financial aspects of each application. The Special Audits, Review and Compliance Section also may become involved in the review of an amendment depending on the aspect of the amendment request.

CERTIFICATE OF NEED APPLICATION PROCESS

The following discussion briefly describes the steps an applicant follows in order to apply for a CON.

Letter of Intent. An applicant must file a letter of intent (LOI) with MDCH and the regional CON review agency, if any. The LOI is a form supplied by MDCH. MDCH provides an applicant with the necessary application forms based on the information contained in the LOI form.

Application. An applicant files the application forms with MDCH and the regional CON review agency, if any, on a designated application date. MDCH reviews an application to determine if it is complete. If not complete, additional information is requested. For nonsubstantive reviews, the application is deemed complete, or received, when the additional information has been provided. For substantive individual and comparative reviews in which additional information is requested, the application is deemed complete or received the first working day of the month following the receipt of the application. For nonsubstantive and substantive reviews, the review cycle starts after an application is deemed complete or received.

Review Types and Time Frames. There are three review types: nonsubstantive, substantive individual, and comparative. Nonsubstantive reviews that involve projects such as certain equipment replacements and changes in ownership do not require a full review. Substantive individual reviews involve projects that require a full review but do not involve a resource limited by a CON review standard. Comparative reviews involve situations where two or more applicants are competing for a resource limited by a CON review standard, such as hospital or nursing home beds. The maximum review time frames for each review type, from the date an application is deemed complete or received until a proposed decision is issued, are: 45 days for nonsubstantive, 120 for substantive individual, and 150 days for comparative reviews. The comparative review time frame includes an additional 30-day period for determining if a comparative review is necessary. Whenever this determination is made, the review cycle begins for comparative reviews.

Review Process. MDCH reviews the application. The CON Section and the Special Audits, Review and Compliance Section review each application separately. Each office completes a staff program report documenting its analysis and findings of compliance with the statutory review criteria, as set forth in Section 22225 of the CON law and the CON review standards.

Proposed Decision. The Department issues a proposed decision to the CON applicant within the required time frame. This decision is binding unless reversed by the Department director or, in the case of a denial, the decision is appealed as described below. In the case of a comparative review, a single decision is issued for all applications in the same comparative group.

Acceptance and Appeal of Decision. If the proposed decision is an approval, a final decision must be signed by the Director within five business days. If the proposed decision is a disapproval, an applicant may request a hearing within 15 days of receipt of the proposed decision. If a hearing is requested, the final decision is not issued by the MDCH director until after completion of the hearing. If no hearing is requested, the MDCH director issues the final decision.

Types of Certificate of Need Reviews

The Certificate of Need Administrative Rules (the "Rules") establish three types of project reviews: nonsubstantive, substantive individual, and comparative substantive. As discussed in the previous section, the Rules specify the time frames by which the Department must issue its proposed decision related to a CON application. The time allowed varies based on the type of review.

Nonsubstantive

Table 1 provides an analysis of nonsubstantive review decisions, by project type, issued beginning FY1998 through FY2002. Nonsubstantive reviews involve projects that are subject to CON review but, based upon the department's determination, do not warrant a full review. The following describes some of the types of projects that potentially would be eligible for review on a nonsubstantive basis:

- ' Acquisition of an existing health facility;
- Replacement of existing licensed hospital or nursing home beds at the same licensed site:
- Change of existing licensed hospital or nursing home beds from one licensed site to another licensed site in the same area and within the applicable replacement zone and which involves a capital expenditure of less than \$2,510,000;
- Addition of host sites to an existing mobile equipment network, changing central service coordinators, or reconfiguring an existing mobile equipment network;
- Replacement or upgrade of medical equipment associated with the provision of a covered clinical service if the project meets the volumes required by the CON review standards and associated construction and/or renovation costs are less than \$2,510,000:
- Acquisition or relocation of an existing megavoltage radiation therapy service and/or unit, acquisition of an existing surgical service, or acquisition of an existing MRI service and/or unit.

The Administrative Rules allow the Department up to 45 days from the date an application is deemed complete to issue a proposed decision. Reviewing acquisitions and equipment replacements on a nonsubstantive basis allows an applicant to receive a decision in a timely fashion while still being required to meet current CON requirements, including quality assurance standards.

TABLE 1 NONSUBSTANTIVE REVIEW FINAL DECISIONS FY1998 - FY2002								
PROJECT TYPE	FY1998	FY1999	FY2000	FY2001	FY2002			
Facility Acquisition	67	40	33	20	26			
Equipment Replacement/Relocation	39	62	54	62	44			
Other	10	7	5	4	9			
TOTALS	116	109	92	86	79			

Substantive Individual

Substantive individual review projects require a full review but do not involve a limitation on the number of beds or services. An example of a project reviewed on a substantive individual basis is the initiation of a covered clinical service such as open heart surgery. The Department must issue its proposed decision within 120 days of the date a substantive individual application is deemed complete or received.

Comparative

Comparative reviews involve situations where two or more applications are competing for a limited resource such as hospital beds, nursing home beds, or lithotripsy services. A proposed decision on a project that is subject to comparative review must be issued by the Department no later than 120 days after the review cycle begins. The review cycle begins when the determination is made that the project requires a comparative review. According to CON Administrative Rules, the Department has the additional 30 days to determine if, in aggregate, all of the applications submitted on a comparative window date exceed the current need, therefore, requiring a comparative review. A comparative window date is one of the three dates during the year on which projects potentially subject to comparative review must be filed. Those dates are February 1, June 1, and October 1 (or the first working day following any of those dates if it falls on a holiday or a weekend).

Section 22229 established the services that were subject to comparative review. Pursuant to Part 222, the CON Commission may, and has, changed the list of services reviewed on a comparative basis. **Figure 1** delineates services currently subject to comparative review.

FIGURE 1: Services Subject to Comparative Review								
Neonatal Intensive Care								
Extracorporeal Shock Wave Lithotripsy (ESWL)								
Hospital Beds								
Hospital Beds for HIV Infected Individuals								
Nursing Home Beds								
Nursing Home Beds for Special Population Groups								
Psychiatric Beds								
Transplantations (excluding Pancreas)								

Table 2 provides a historical overview of the average review time by review type. This table also includes a breakdown of applications potentially subject to comparative review and, consequently, filed on a comparative window date. In situations where no competing applications were filed on the same window date, a comparative review was not necessary, and the applications were reviewed on a substantive individual basis.

TABLE 2 PROPOSED DECISIONS BY REVIEW TYPE AND AVERAGE NUMBER OF DAYS IN REVIEW CYCLE FY1998-FY2002

	FY1	998	FY1999		FY2000		FY2001		FY2002	
REVIEW TYPE	Total Decisions	Avg. Days								
Nonsubstantive	105	27	101	27	70	23	75	29	59	33
Substantive Individual	40	114	44	113	37	118	60	114	88	115
Potential Comparative	11	110	1	57	1	120	7	83	12	119
Comparative	2	120	2	120	0	0	4	120	36	145
TOTALS*	158		148		108		146		195	

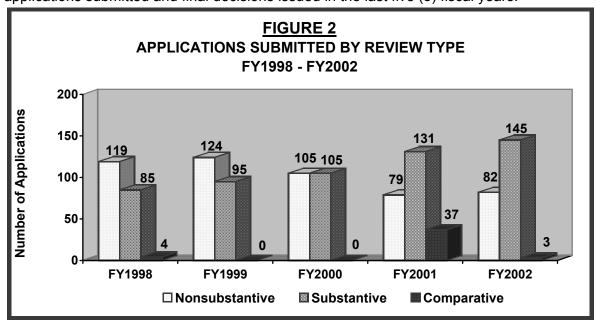
^{*}Excludes projects extended during the review cycle even though the proposed decision on the extended project may have been issued during the FY.

Table 3 compares the number of applications submitted to the Department and the number of final decisions issued in the five (5) most recent fiscal years.

TABLE 3 APPLICATIONS SUBMITTED AND FINAL DECISIONS FY1998 - FY2002								
FY1998 FY1999 FY2000 FY2001 FY								
Applications Submitted	208	219	210	247	230			
Final Decisions	195	186	168	198	224			

Note: Not all applications received in a given year receive a decision in that same fiscal year.

Figures 2 and 3 illustrate the changes in the project review types in terms of applications submitted and final decisions issued in the last five (5) fiscal years.



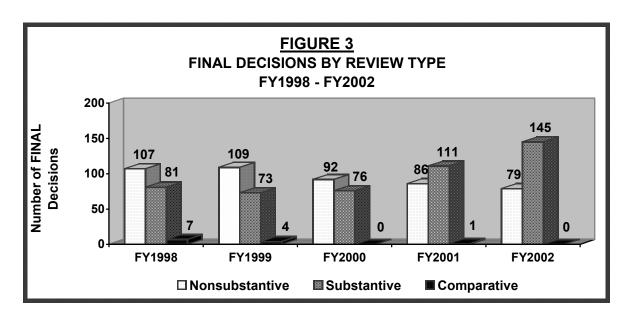


Table 4 provides data from FY1998 through FY2002 on the number and percent of applications that were incomplete when submitted to the Department. Prior to actually reviewing an application, the Department examines each application to determine if all of the necessary information requested in response to the Letter of Intent has been received as well as if other information is needed to demonstrate compliance with applicable statutory requirements. This phase of the review process--the completeness review--involves approximately 30 days. The Department has up to 15 days to request additional information, and an applicant has up to 15 days to respond to the Department's request.

TABLE 4 INCOMPLETE APPLICATIONS FY1998 - FY2002 FY2002 FY1998 FY1999 FY2000 FY2001 NONSUBSTANTIVE 34 45 25 18 11 Complete 64 Incomplete 85 79 80 68 TOTALS 119 124 105 79 82 Percent Incomplete 71% 64% 76% 86% 78% SUBSTANTIVE INDIVIDUAL Complete 3 1 1 8 43 Incomplete 82 94 104 123 102 **TOTALS** 85 95 105 131 145 96% Percent Incomplete 99% 99% 94% 70% COMPARATIVE Complete 0 0 0 0 0 Incomplete 4 0 0 37 3 TOTALS 4 0 0 37 3 Percent Incomplete 100% 0% 0% 100% 100% **ALL APPLICATIONS** Complete 37 46 26 19 61 Incomplete 171 173 184 228 169 **TOTALS** 208 219 210 247 230 82% Percent Incomplete 79% 88% 92% 73%

Part 222 establishes a two-step decision-making process for CON applications that includes both a proposed decision and a final decision. After an application is deemed complete and reviewed by the CON Section and the Special Audits, Review and Compliance Section, a proposed decision is issued to the applicant and the MDCH director according to the time frames established in the Administrative Rules.

Table 5 compares the number of proposed decisions by decision type made from FY1998 through FY2002.

<u>TABLE 5</u> COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE FY1998 - FY2002									
Approved With Percent Approved Conditions Disapproved TO									
FY1998	177	0	10	5%	187				
FY1999	180	5	4	2%	189				
FY2000	153	5	8	5%	166				
FY2001	178	5	27	13%	210				
FY2002	203	8	48	19%	259				

Table 6 analyzes the disposition of proposed disapprovals issued from FY1994 through FY2002.

TABLE 6 DISPOSITION OF PROPOSED DECISIONS TO DISAPPROVE AS OF SEPTEMBER 30, 2002												
	Proposed Disapproval	Withdrawn	Final Disapproval	Final Approval		No Final Decision as of 9-30-02						
FY1994	27	6	6	14	1	4%						
FY1995	17	9	2	6	0	0%						
FY1996	14	3	8	3	0	0%						
FY1997	9	2	3	4	0	0%						
FY1998	10	2	3	5	0	0%						
FY1999	4	0	2	2	0	0%						
FY2000	8	1	4	3	0	0%						
FY2001	27	7	16	4	0	0%						
FY2002	48	9	2	5	32	67%						
TOTALS	164	39	46	46	33	20%						

The types of projects still pending final decisions include applications for nursing home changes of ownership, psychiatric beds, hospital beds, mobile magnetic resonance imaging (MRI) services, and positron emission tomography (PET) services. If a proposed decision is a disapproval, an applicant may request an administrative hearing that suspends the time frame for issuing a final decision. After a proposed disapproval is issued, an applicant may request that the Department reconsider its decision. The reconsideration process is an informal process that allows an applicant to submit new information in response to the areas of noncompliance identified by the Department's analysis of an application and the applicable statutory requirements. The majority of projects that have not received a final decision continue to pend because applicants are in the process of developing additional information to satisfy the requirements for approval.

FINAL DECISIONS

The Director of the Department of Community Health issues a final decision on a Certificate of Need application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1), the Director may issue a decision to approve an application, disapprove an application, or approve an application with conditions or stipulations. If an application is approved with conditions, the conditions must be explicit and must relate to the proposed project or the applicable provisions of Part 222. If approved with stipulations, the requirements must be germane to the proposed project and already agreed to by the applicant. The conditions must specify a time period within which the conditions shall be met, and that time period cannot exceed one year after the date the decision is rendered.

This section of the report provides a series of tables summarizing final decisions for each of the review thresholds for which a CON is required. It should be noted that the following tables will not equal the number of final decisions in **Table 3**, as many applications fall into more than one category.

Acquire, Begin Operation of, or Replace a Health Facility

Table 7 identifies applications reviewed under Section 22209(1)(a): "Acquire an existing health facility or begin operation of a health facility at a site that is not currently licensed for that type of health facility." Under Part 222, a health facility is defined as a general hospital, a hospital long-term care unit, a psychiatric hospital or unit, a partial hospitalization psychiatric program, a nursing home, a freestanding surgical outpatient facility (FSOF), and a health maintenance organization under limited circumstances. This review category includes projects where a new or replacement health facility is proposed to be constructed or developed and projects involving the acquisition of an existing health facility through purchase or lease.

Change in Bed Capacity

Table 8 summarizes final decisions made on applications subject to review under Section 22209(1)(b): "Make a change in the bed capacity of a health facility." This category is defined to include an increase in the number of licensed hospital, nursing home, or psychiatric beds; a change in the licensed use; and the physical relocation of existing licensed beds from one geographic location to another without an increase in the total number of beds.

Covered Clinical Services

Table 9 includes projects reviewed under Section 22209(1)(c): "Initiate, replace, or expand a covered clinical service."

TABLE 7 SUMMARY OF FINAL DECISIONS ACQUIRE, BEGIN OPERATION OF, OR REPLACE A HEALTH FACILITY FY1998 - FY2002

1 1 1330 - 1 1 2002								
	FY1998	FY1999	FY2000	FY2001	FY2002			
Type of Health Facility			Approved					
Hospital	13	11	3	6	9			
Nursing Home/HLTCU	33	29	32	26	27			
Psychiatric Hospital/Unit	7	2	3	1	1			
Partial Hosp Psych Program	3	1	0	0	0			
Freestanding Surg OP Facility	10	6	7	2	9			
TOTAL APPROVED	66	49	45	35	46			
			Disapproved					
Hospital	0	0	0	0	2			
Nursing Home/HLTCU	3	0	0	0	0			
Psychiatric Hospital/Unit	0	0	0	0	0			
Partial Hosp Psych Program	0	0	0	0	0			
Freestanding Surg OP Facility	1	0	1	0	0			
TOTAL DISAPPROVED	4	0	1	0	2			

TABLE 8 SUMMARY OF FINAL DECISIONS FOR CHANGES IN BED CAPACITY FY1998 – FY2002									
Type of Health Facility	Type of Health Facility FY1998 FY1999 FY2000 FY2001 FY2002								
			Approved						
Hospital	7	8	4	4	4				
Nursing Home/HLTCU	13	10	5	7	17				
Psychiatric Hospital/Unit	3	1	0	0	0				
TOTAL APPROVED	23	19	9	11	21				
			Disapproved						
Hospital	0	0	0	0	1				
Nursing Home/HLTCU	3	1	0	2	0				
Psychiatric Hospital/Unit	0	0	0	0	0				
TOTAL DISAPPROVED	3	1	0	2	1				

TABLE 9 SUMMARY OF FINAL DECISIONS FOR COVERED CLINICAL SERVICES FY1998 - FY2002								
Type of Covered Clinical Service		FY1999	FY2000	FY2001	FY2002			
Approved								
Open Heart Surgery	1	1	0	2	0			
Extrarenal Transplants	1	0	0	0	0			
Special Radiological (Includes Cardiac								
Cath) ¹	10	10	8	18	22			
Megavoltage Radiation Therapy 1	9	14	13	19	5			
Specialized Inpatient Psychiatric	4	0	1	0	1			
Partial Hospital Psychiatric	13	4	1	1	0			
NICU	2	0	1	0	1			
Surgical Facilities (ORs)	9	15	12	9	20			
Air Ambulance ¹	0	3	0	0	2			
PET Scanners ¹ Fixed	0	0	1	2	2			
Mobile				0	0			
Host				0	0			
CT Scanners ¹ Fixed	27	34	31	47	38			
Mobile	1	0	0	1	1			
Host	13	4	4	4	4			
MRI ¹ Fixed	6	8	7	8	13			
Mobile	2	2	3	5	8			
Host	3	8	11	12	8			
UESW Lithotripsy ¹ Fixed	0	0	2	0	0			
Mobile	0	1	0	1	2			
Host	1	9	13	0	20			
TOTAL APPROVED	53	66	71	129	147			
			Disapproved					
Open Heart Surgery	0	0	0	0	0			
Extrarenal Transplants	0	0	0	0	0			
Special Radiological (Includes Cardiac Cath) ¹	0	0	0	0	0			
Megavoltage Radiation Therapy ¹	0	0	1	1	0			
Specialized Inpatient Psychiatric	0	0	0	0	0			
Partial Hospital Psychiatric	1	0	0	0	0			
NICU	0	0	0	0	0			
Surgical Facilities (ORs)	1	0	1	0	0			
Air Ambulance ¹	0	0	1	0	0			
PET Scanners ¹	0	0	0	0	0			
Mobile				1	0			
Host				7	0			
CT Scanners ¹ Fixed	0	0	1	1	0			
Mobile	0	0	0	0	0			
Host	0	0	0	0	0			
MRI ¹ Fixed	0	0	0	0	0			
Mobile	0	0	0	0	1			
Host	0	0	0	0	4			
UESW Lithotripsy ¹ Fixed	0	0	0	0	0			
Mobile	0	0	0	0	0			
Host	0	0	0	0	0			
TOTAL DISAPPROVED	0	0	1	10	5			
1	U	U		10	J			

The number of decisions does not necessarily represent new capacity. Many applications involve replacement equipment or the addition of a host site to an existing mobile network.

Covered Capital Expenditures

Table 10 identifies the number of projects involving the fourth review threshold--a covered capital expenditure--listed by the type of health facility. Under Section 22209(1)(d), a person must obtain a CON for a covered capital expenditure. The capital expenditure threshold figures for clinical and nonclinical areas were increased, on January 1, 2002, to \$2,510,000 and \$3,765,000, respectively, pursuant to the requirements of Section 22221(g). In computing a capital expenditure, the cost of non-fixed medical equipment (any medical equipment not on the list of covered clinical services) is excluded. In July 1993, the definition of a covered capital expenditure was amended to eliminate projects limited solely to the acquisition of non-fixed, non-medical equipment (telephones, computers, etc.). Typical examples of covered capital expenditure projects include construction, renovation, or the addition of space to accommodate increases in patient service volumes.

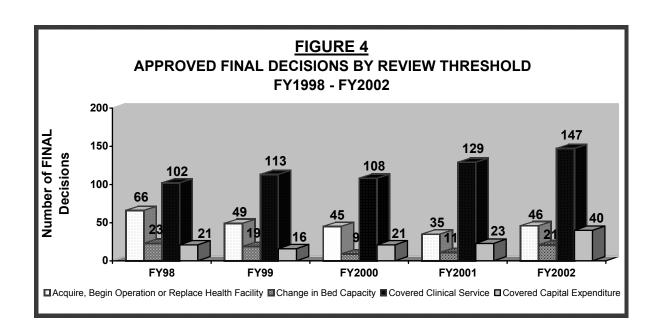
TABLE 10 SUMMARY OF FINAL DECISIONS FOR COVERED CAPITAL EXPENDITURES FY1998 - FY2002								
Type of Health Facility	FY1998	FY1999	FY2000	FY2001	FY2002			
			Approved					
Hospital	18	9	15	18	28			
Nursing Home/HLTCU	3	5	2	4	11			
Psychiatric Hospital/Unit/PHP	0	0	2	0	0			
FSOF	0	2	2	1	1			
TOTALS	21	16	21	23	40			
			Disapproved					
Hospital	0	0	0	0	1			
Nursing Home/HLTCU	0	1	0	1	0			
Psychiatric Hospital/Unit/PHP	0	0	0	0	0			
FSOF	0	0	0	0	0			
TOTALS	0	1	0	1	1			

Table 11 and Figures 4 and 4A provide summaries of FY2002 final decisions by decision type and review threshold.

type and review an contra	typo and review amounds.					
TABLE 11 FINAL DECISION TYPE BY SUMMARY OF THRESHOLDS FY1998 - FY2002						
Decision Type	FY1998	FY1999	FY2000	FY2001	FY2002	
Approved	212	197	183	198	254	
Disapproved 9 2 5 13 9						
TOTAL FINAL DECISIONS	221	199	188	211	263	

Note: Although there were 224 CON final decisions in FY2002, when analyzed by review threshold, there were 263 decisions since some applications involve more than one threshold.

The majority of final decisions involved nursing home change of ownership projects and projects involving covered clinical services. The applications for covered clinical services primarily involve equipment acquisitions, both new and replacement. Few projects for new facilities or beds were proposed. Since the capital expenditure threshold was increased to \$3,765,000 for non-clinical areas in 2002, fewer construction projects are subject to review. Many construction projects previously subject to review involved changes to health facilities within limited areas of the facility. Since the 1988 amendments, only capital expenditure projects involving major changes at health facilities are subject to review.



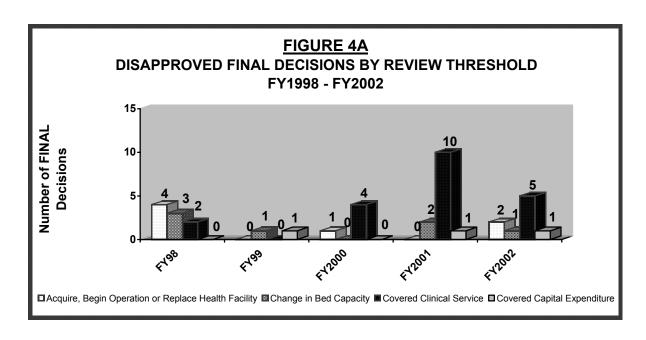
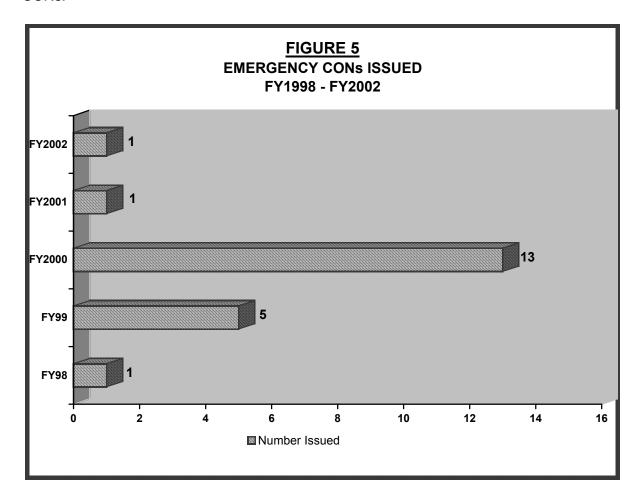


Table 12 provides a comparison of the total number of final decisions and total project costs by decision type.

TABLE 12 COMPARISON OF FINAL DECISIONS BY DECISION TYPE FY1998 - FY2002					
	Approved	Approved With Conditions	Disapproved	TOTALS	
	тфрина	Number of Final	•		
FY1998	185	1	9	195	
FY1999	178	6	2	186	
FY2000	153	11	4	168	
FY2001	182	4	12	198	
FY2002	210	6	8	224	
Total Project Costs					
FY1998	\$853,035,470	\$50,000	\$8,496,000	\$861,581,470	
FY1999	\$461,603,485	\$42,956,484	\$246,910	\$504,806,879	
FY2000	\$467,085,573	\$16,666,330	\$5,818,762	\$489,570,665	
FY2001	\$974,220,693	\$3,205,149	\$9,316,888	\$986,742,730	
FY2002	\$1,030,698,218	\$11,898,680	\$22,141,586	\$1,064,738,484	

Figure 5 shows the number of emergency CONs issued from FY1998 through FY2002. The Department is authorized by Section 22235 of the Public Health Code to issue emergency CONs.



AMENDMENTS

The CON Administrative Rules allow the Department to amend a Certificate of Need for projects less than 100 percent complete. The Department has the authority to decide when an amendment is appropriate or when the proposed change is significant enough to require a separate application. Typical reasons for requesting amendments to approved CONs include the following:

- Cost overruns. The Rules allow the actual cost of a project to exceed the approved amount by 15 percent of the first \$1 million and 10 percent of all costs over \$1 million. Fluctuations in construction costs can cause projects to exceed approved amounts.
- Changes in the scope of a project. An example is the addition of construction or renovation required by regulatory agencies to correct existing code violations that an applicant did not anticipate in planning the project.
- **Changes in financing.** Applicants may decide to pursue a financing alternative better than the financing that was approved in the CON.

The revised Rules, effective March 27, 1996, state that the review period for a request to amend an approved Certificate of Need shall not be longer than the original review period for the application. There were 12 amendments approved in FY2002.

Table 13 provides a comparison of summary information from FY1998 through FY2002 for various stages of the CON process. Data for FY1998 through FY2002 involve applications filed under Part 222.

TABLE 13 CON ACTIVITY COMPARISON FY1998 - FY2002						
	Number of Applications	% Change From Previous Year	Total Project Costs	% Change From Previous Year		
		Letters of Intent Receive	ed			
FY1998	298	-16%	\$1,042,744,497	+14%		
FY1999	300	+1%	\$739,220,325	-29%		
FY2000	342	+14%	\$1,275,193,745	+73%		
FY2001	459	+34%	\$1,564,993,008	+23%		
FY2002	447	-3%	\$1,374,379,486	-12%		
	Applications Submitted					
FY1998	208	-18%	\$867,808,689	-6%		
FY1999	219	+5%	\$629,980,505	-27%		
FY2000	210	-4%	\$1,055,728,757	+68%		
FY2001	247	+18%	\$1,165,903,161	+10%		
FY2002	230	-7%	\$1,078,408,796	-8%		
		Proposed Decisions Issu	ed			
FY1998	187	-30%	\$804,960,578	-14%		
FY1999	189	+1%	\$496,393,126	-38%		
FY2000	166	-12%	\$512,858,454	+3%		
FY2001	210	+27%	\$981,894,585	+91%		
FY2002	259	+23%	\$1,483,467,795	+51%		
Final Decisions Issued						
FY1998	195	-28%	\$861,581,470	-6%		
FY1999	186	-5%	\$504,806,879	-41%		
FY2000	168	-10%	\$489,570,665	-3%		
FY2001	198	+18%	\$986,742,730	+102%		
FY2002	224	+13%	\$1,064,738,484	+8%		

Figure 6 illustrates overall Certificate of Need activity for FY1998 through FY2002. Activity has been relatively stable from FY1998 through FY2000 in terms of applications, proposed decisions, and final decisions with a gradual increase of proposed and final decisions from FY2000-FY2002. Letters of intent remained relatively stable from FY1998 through FY2000 but increased significantly for FY2001 and remained relatively stable for FY2002.

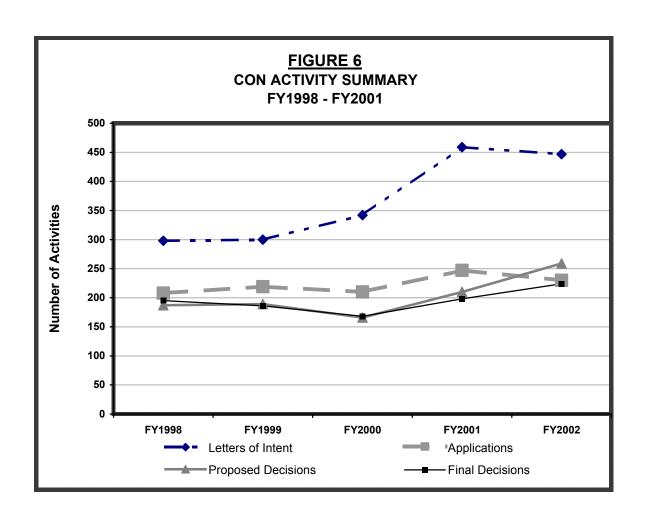
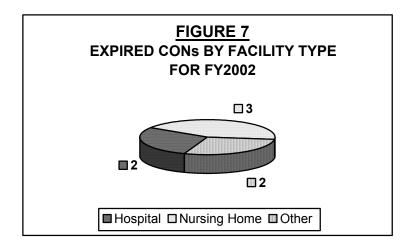


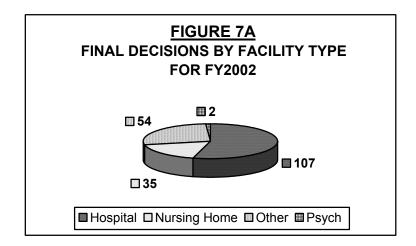
Table 14 analyzes the number and types of CONs, by type of health facility that expired from FY1998 through FY2002. During FY2002, a total of seven (7) CONs were expired by the Department because the applicant did not implement the CON.

TABLE 14 SUMMARY OF EXPIRED CONS FY1998 - FY2002					
	FY1998	FY1999	FY2000	FY2001	FY2002
FACILITY TYPE / PROJECT TYPE	TYPE Number of Expired CONs				
Hospital					
Add Additional CT Scanner					
Add/Relocate MRT	1	1			
Add Cardiac Cath		1	1		
Mobile CT Scanners					
Replace/Upgrade 2 CT Scanners					
CT Scanner					
Host Site for Mobile MRI					
Mobile MRI Unit					
Pancreas Transplant Service					
Bone Marrow Transplant Service					
Liver Transplant Service					
Construction/Renovation				1	
Add/Renovate ORs					
Linear Accelerator					
AIDS Hospital					
Bed Replacement				1	
Open Heart / Therapeutic Cardiac Cath					
Acquisitions		1			2
Nursing Home					
Acquisitions		5	2	1	
Replace Nursing Home	1				
Bed Additions					
New Nursing Homes	1	2	1		2
Addition of Special Population Beds					1
Bed Replace/Relocate within Zone	2		1		
Psychiatric Hospital/Partial Program					
New Partial Hospital Programs					
Add PHP	1		1		
Relocate Partial Hospital Program					
Major Construction and Renovation					
Acquisition				1	1
Addition of Psychiatric Beds					
Other					
New FSOF		2		1	1
Purchase FSOF		_	1		
Add CT Scanner	1				
Host Site for Mobile CT Scanner					
Acquisition of MRT Unit					
Relocate MRT Unit	1				
CT Scanner Replacement					
TOTALS	8	12	7	5	7
TOTALO	0	12		3	

The majority of CONs that expire involve nursing homes. As shown in **Table 14**, the types of projects that are never implemented vary significantly.

Figure 7 illustrates expired CONs by facility type for FY2002. For comparison, **Figure 7A** illustrates the number of final decisions by facility type.





COMPLIANCE ACTIONS

There were 184 projects requiring follow-up for FY2002 based on the Department's Monthly Follow-up/Monitoring Report as shown in **Table 15**. As a result, seven (7) CONs were expired as shown in **Table 14**. Further, pursuant to R 325.9419 of the CON Administrative Rules, no compliance orders were issued in FY2002.

TABLE 15 COMPLIANCE ACTIONS FY2001 - FY2002				
	FY2001	FY2002		
Projects Requiring Follow-up	169	184		
Compliance Orders Issued	0	0		

Analysis of Certificate of Need Program Fees and Costs

Section 20161(3) sets forth the fees to be collected for CON applications. The fees are based on total project costs and are set forth in **Table 16** below.

TABLE 16 CON APPLICATION FEES				
Total Project Costs	CON Application Fee			
\$0 to 150,000	\$ 750			
\$150,001 to 1,500,000	\$2,750			
\$1,500,001 and above	\$4,250			

Table 16A analyzes the number of applications according to which fee was assessed.

TABLE 16A NUMBER OF CON APPLICATIONS BY FEE FY1998 - FY2002					
CON Fee	FY1998	FY1999	FY2000	FY2001	FY2002
\$ 0	74	17	15	2	1
\$ 750	46	40	38	64	42
\$2,750	57	61	58	61	65
\$4,250	91	101	99	120	122
TOTALS	268	219	210	247	230

Note: No CON fees are required for the following: Emergency CONs and swing beds.

Table 17 provides information on CON costs and source of funds for FY2001 through FY2002.

<u>TABLE 17</u> CON PROGRAM COST AND REVENUE SOURCES FOR FY2001 – FY2002				
	FY2000	FY2001	FY2002	
Program Cost	\$1,247,752	\$1,399,443	\$1,578,640	
Application Fees	\$583,516	\$731,259	\$721,650	
Fees % of Costs	47%	52%	46%	

Source: MDCH Budget and Finance Administration

Section 22215(6) states "If the reports received under section 22221(f) indicate that the certificate of need application fees collected under section 20161(2) have not been within 10% of 1/2 the cost to the department of implementing this part, the commission shall make recommendations regarding the revision of those fees so that the certificate of need application fees collected equal approximately 1/2 of the cost to the department of implementing this part." The following fee information for FY2002 indicates the CON program is in compliance with Section 22215(6).

FY2002 Total Costs	\$1,578,640
50% of Total Costs	\$789,320
Less FY2002 Fee Revenue	\$721,650
Fee Revenue Deficit	\$67,670

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2002, the Certificate of Need Commission revised the review standards for Positron Emission Tomography (PET) Scanner Services, Magnetic Resonance Imaging (MRI) Services, Hospital Beds, and Pancreas Transplantation Services.

The revisions to the CON Review Standards for PET Scanner Services received final approval by the CON Commission on December 11, 2001 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective February 25, 2002. The revised standard changes addressed the methodology, included requirements for mobile PET services, eliminated comparative review, made the revised standards prospective, and confirmed that PET/CT scanner hybrids are included in the definition of "PET scanner."

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on March 12, 2002 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective May 24, 2002. The revised standard changes addressed the requirements for conversion from mobile to fixed services.

The revisions to the CON review standards for hospital beds received final approval by the CON Commission on May 14, 2002 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective July 1, 2002. The revised standard changes addressed the replacement of a licensed non-rural hospital within the hospital subarea but outside of the 2-mile replacement zone. Further, the proposed changes addressed the long-term (acute) care (LTAC) hospitals to: 1) Clarify that an LTAC hospital may arrange for medically necessary services not offered by the LTAC hospital consistent with Medicare regulations; and 2) Clarify ability of lessor hospital to reacquire beds formerly leased to an LTAC hospital and to use them as general acute care beds.

The revisions to the CON review standards for MRI services received final approval by the CON Commission on May 14, 2002 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective July 1, 2002. The revised standards changes addressed the methodology and issues related to access and concerns for pediatrics vs. adults.

The revisions to the CON review standards for Pancreas Transplantation services received final approval by the CON Commission on September 26, 2002 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective December 23, 2002. The revised standard changes updated select provisions in the requirements for approval and in the project delivery requirements sections to correspond with current knowledge and practices.

APPENDIX I - CERTIFICATE OF NEED COMMISSION

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